

WE CLAIM:

1. An apparatus for testing one or more sterilization indicators by contacting them under controlled sterilization conditions with a flowing antimicrobial gas comprising hydrogen peroxide vapor, the apparatus comprising:

(a) a chamber in which the one or more sterilization indicators can be contacted with the flowing antimicrobial gas;

(b) means for rapidly placing the one or more sterilization indicators in the chamber while the flow of the antimicrobial gas in the chamber is substantially continuous and the concentration of hydrogen peroxide in the antimicrobial gas is substantially constant;

(c) means for continuing to flow the antimicrobial gas in the chamber to contact the one or more sterilization indicators from substantially the moment they are placed in the chamber, the contact being under substantially uniform conditions for the desired contact time, the flow of the antimicrobial gas during the contact being substantially continuous and the concentration of hydrogen peroxide in the antimicrobial gas during the contact being substantially constant; and

(d) means for rapidly removing the one or more sterilization indicators from the chamber after the desired contact time of the one or more sterilization indicators with the antimicrobial gas has elapsed.

2. The apparatus of claim 1 further comprising means for pre-treating the one or more sterilization indicators before their contact with the antimicrobial gas has commenced.

3. The apparatus of claim 1 further comprising means for post-treating the one or more sterilization indicators after they have been removed from the chamber.

4. The apparatus of claim 1 further comprising means for pre-treating the one or more sterilization indicators before their contact with the flowing antimicrobial gas has commenced and means for post-treating them after their contact with the flowing antimicrobial gas has halted.

5. The apparatus of claim 4 wherein the means for pre-treating and the means for post-treating comprise at least some of the same members.

6. The apparatus of claim 5 further comprising an antechamber wherein the means for pre-treating and the means for post-treating each comprise the antechamber.

7. The apparatus of claim 6 further comprising a movable member and means for moving the movable member from the chamber to the antechamber and from the antechamber to the chamber.

8. The apparatus of claim 7 wherein the means for rapidly placing the one or more sterilization indicators in the chamber and the means for rapidly removing the one or more

sterilization indicators from the chamber after the desired contact time has elapsed are the same and each comprises the movable member.

9. The apparatus of claim 1 further comprising means to maintain the one or more sterilization indicators in a predefined volume in the chamber.

5 10. The apparatus of claim 9 further comprising means to flow substantially all of the antimicrobial gas flowing into the chamber through the predefined volume.

11. The apparatus of claim 1 further comprising means for monitoring the hydrogen peroxide concentration of the antimicrobial gas.

10 12. The apparatus of claim 1 further comprising means for maintaining the contact of the antimicrobial gas with the sterilization indicators at a desired temperature.

13. The apparatus of any of claims 1 to 12 further comprising antimicrobial gas generating means for providing the flowing antimicrobial gas comprising hydrogen peroxide vapor, the antimicrobial gas generating means comprising:

(a) a vaporization plenum having an inner surface;

15 (b) means for breaking a vaporizable liquid comprising hydrogen peroxide into fine particles and for flowing the fine particles in the vaporization plenum, the bulk flow of the fine particles flowing in the vaporization plenum being in a first direction;

20 (c) means for flowing a gas or vapor comprising a first substance in the vaporization plenum and for flowing at least some of the first substance between the inner surface of the vaporization plenum and substantially all of the fine particles to create a curtain of first substance between the inner surface of the vaporization plenum and substantially all of the fine particles, the bulk flow of the first substance in the vaporization plenum flowing in substantially the same direction as the first direction; and

25 (d) means for causing substantially all of the fine particles to vaporize in the flow of the first substance to produce a substantially continuous flow of a gas-phase mixture of the first substance and vaporized hydrogen peroxide of substantially constant hydrogen peroxide concentration as a function of time, the antimicrobial gas comprising the gas-phase mixture.

14. The apparatus of claim 13 wherein the antimicrobial gas generating means is oriented so that the first direction is up and substantially vertical.

30 15. A method for testing one or more sterilization indicators by contacting them under controlled sterilization conditions with a flowing antimicrobial gas comprising hydrogen peroxide vapor, the method comprising:

(a) rapidly placing the one or more sterilization indicators in the chamber of the apparatus of claim 1 or 4 while the flow of the antimicrobial gas in the chamber is substantially

continuous and the concentration of hydrogen peroxide in the antimicrobial gas is substantially constant;

(b) continuing to flow the antimicrobial gas in the chamber to contact the one or more sterilization indicators from substantially the moment they are placed in the chamber, the contact being under substantially uniform conditions for the desired contact time, the flow of the antimicrobial gas during the contact being substantially continuous and the concentration of hydrogen peroxide in the antimicrobial gas during the contact being substantially constant; and

(c) rapidly removing the one or more sterilization indicators from the chamber after the desired contact time of the one or more sterilization indicators with the antimicrobial gas has elapsed.

16. An apparatus for testing one or more sterilization indicators by contacting them under controlled sterilization conditions with a flowing antimicrobial gas comprising hydrogen peroxide vapor, the apparatus comprising:

(a) a chamber in which the one or more sterilization indicators can be contacted with the flowing antimicrobial gas;

(b) means for suddenly commencing and then continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber under substantially uniform conditions for the desired contact time, the flow of the antimicrobial gas in the chamber during the contact being substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas during the contact being substantially constant; and

(c) means for suddenly halting the contact of the antimicrobial gas with the sterilization indicators after the desired contact time has elapsed.

17. The apparatus of claim 16 further comprising means for pre-treating the one or more sterilization indicators before their contact with the flowing antimicrobial gas has commenced.

18. The apparatus of claim 16 further comprising means for post-treating the one or more sterilization indicators after their contact with the flowing antimicrobial gas has halted.

19. The apparatus of claim 16 further comprising means for pre-treating the one or more sterilization indicators before their contact with the flowing antimicrobial gas has commenced and means for post-treating them after their contact with the flowing antimicrobial gas has halted.

20. The apparatus of claim 19 wherein the means for pre-treating and the means for post-treating comprise at least some of the same members.

21. The apparatus of claim 20 further comprising an antechamber wherein the means for pre-treating and the means for post-treating each comprise the antechamber.

22. The apparatus of claim 16 further comprising means for monitoring the hydrogen peroxide concentration of the antimicrobial gas.

23. The apparatus of claim 16 wherein the means for suddenly commencing and then continuing the contact of the flowing antimicrobial gas with the sterilization indicators comprises means for rapidly placing and maintaining the one or more sterilization indicators in the chamber while the flow of the antimicrobial gas in the chamber is substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas is substantially constant.

24. The apparatus of claim 16 wherein the means for suddenly halting the contact of the flowing antimicrobial gas with the sterilization indicators after the desired contact time has elapsed comprises means for rapidly removing the one or more sterilization indicators from the chamber after the desired contact time has elapsed.

25. The apparatus of claim 16 further comprising means to maintain the one or more sterilization indicators in a predefined volume in the chamber.

26. The apparatus of claim 25 further comprising means to flow substantially all of the antimicrobial gas flowing into the chamber through the predefined volume.

27. The apparatus of any of claims 16 to 26 further comprising antimicrobial gas generating means for providing the flowing antimicrobial gas comprising hydrogen peroxide vapor, the antimicrobial gas generating means comprising:

- (a) a vaporization plenum having an inner surface;
- (b) means for breaking a vaporizable liquid comprising hydrogen peroxide into fine particles and for flowing the fine particles in the vaporization plenum, the bulk flow of the fine particles flowing in the vaporization plenum being in a first direction;
- (c) means for flowing a gas or vapor comprising a first substance in the vaporization plenum and for flowing at least some of the first substance between the inner surface of the vaporization plenum and substantially all of the fine particles to create a curtain of first substance between the inner surface of the vaporization plenum and substantially all of the fine particles, the bulk flow of the first substance in the vaporization plenum flowing in substantially the same direction as the first direction; and

(d) means for causing substantially all of the fine particles to vaporize in the flow of the first substance to produce a substantially continuous flow of a gas-phase mixture of the first substance and vaporized hydrogen peroxide of substantially constant hydrogen peroxide concentration as a function of time, the antimicrobial gas comprising the gas-phase mixture.

28. The apparatus of claim 27 wherein the antimicrobial gas generating means is oriented so that the first direction is up and substantially vertical.

29. A method for testing one or more sterilization indicators by contacting them under controlled sterilization conditions with a flowing antimicrobial gas comprising hydrogen peroxide vapor, the method comprising:

(a) placing them in the chamber of the apparatus of claim 16 or 19;

(b) suddenly commencing and then continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber under substantially uniform conditions for the desired contact time, the flow of the antimicrobial gas in the chamber during the contact being substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas during the contact being substantially constant; and

(c) suddenly halting the contact of the antimicrobial gas with the sterilization indicators after the desired contact time has elapsed.

30. An apparatus for testing sterilization processes that use a flowing antimicrobial gas comprising hydrogen peroxide vapor under controlled sterilization conditions, or for testing materials for such processes under controlled sterilization conditions, or for testing both such processes and such materials under controlled sterilization conditions, the materials comprising one or more articles, the apparatus comprising:

(a) a chamber in which the antimicrobial gas is flowed to provide contact of any one or more of the articles with the antimicrobial gas when articles are in the chamber;

(b) means for flowing the antimicrobial gas in the chamber to contact any such one or more articles under substantially uniform conditions for the desired time, the flow of the antimicrobial gas in the chamber during the desired time being substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas during the desired time being substantially constant; and

(c) means for halting the flow of the flowing antimicrobial gas after the desired time has elapsed.

31. The apparatus of claim 30 wherein means (b) comprises means for suddenly commencing and then continuing the flow of the antimicrobial gas in the chamber.

32. The apparatus of claim 31 wherein the means for suddenly commencing and then continuing the contact of the flowing antimicrobial gas with any one or more articles comprises means for rapidly placing and maintaining the one or more articles in the chamber while the flow of the antimicrobial gas in the chamber is substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas is substantially constant.

33. The apparatus of claim 30 wherein means (c) comprises means for suddenly halting the flow of the antimicrobial gas.

34. The apparatus of claim 33 wherein the means for suddenly halting the contact of the flowing antimicrobial gas with any one or more articles after the desired contact time has elapsed comprises means for rapidly removing the one or more articles from the chamber after the desired contact time has elapsed.

35. The apparatus of claim 30 wherein means (b) comprises means for suddenly commencing and then continuing the flow of the antimicrobial gas in the chamber and means (c) comprises means for suddenly halting the flow of the antimicrobial gas.

36. The apparatus of claim 30 further comprising means for pre-treating any one or more articles placed in the chamber before their contact with the flowing antimicrobial gas has commenced.

37. The apparatus of claim 30 further comprising means for post-treating any one or more articles placed in the chamber after their contact with the flowing antimicrobial gas has halted.

38. The apparatus of claim 30 further comprising means for pre-treating any one or more articles placed in the chamber before their contact with the flowing antimicrobial gas has commenced and means for post-treating any one or more articles placed in the chamber after their contact with the flowing antimicrobial gas has halted.

39. The apparatus of claim 38 wherein the means for pre-treating and the means for post-treating comprise at least some of the same members.

40. The apparatus of claim 39 further comprising an antechamber wherein the means for pre-treating and the means for post-treating each comprise the antechamber.

41. The apparatus of claim 30 further comprising means for monitoring the hydrogen peroxide concentration of the antimicrobial gas.

42. The apparatus of claim 30 further comprising means to maintain any one or more articles placed in the chamber in a predefined volume in the chamber.

43. The apparatus of claim 42 further comprising means to flow substantially all of the antimicrobial gas flowing into the chamber through the predefined volume.

44. The apparatus of any of claims 30 to 43 further comprising antimicrobial gas generating means for providing the flowing antimicrobial gas comprising hydrogen peroxide vapor, the antimicrobial gas generating means comprising:

(a) a vaporization plenum having an inner surface;

(b) means for breaking a vaporizable liquid comprising hydrogen peroxide into fine particles and for flowing the fine particles in the vaporization plenum, the bulk flow of the fine particles flowing in the vaporization plenum being in a first direction;

(c) means for flowing a gas or vapor comprising a first substance in the vaporization plenum and for flowing at least some of the first substance between the inner surface of the

vaporization plenum and substantially all of the fine particles to create a curtain of first substance between the inner surface of the vaporization plenum and substantially all of the fine particles, the bulk flow of the first substance in the vaporization plenum flowing in substantially the same direction as the first direction; and

5 (d) means for causing substantially all of the fine particles to vaporize in the flow of the first substance to produce a substantially continuous flow of a gas-phase mixture of the first substance and vaporized hydrogen peroxide of substantially constant hydrogen peroxide concentration as a function of time, the antimicrobial gas comprising the gas-phase mixture.

10 45. The apparatus of claim 44 wherein the means for flowing a gas or vapor of its subparagraph (c) comprises means for flowing substantially all of the first substance fed to the vaporization plenum between the inner surface of the vaporization plenum and substantially all of the fine particles to create the curtain of first substance.

46. The apparatus of claim 44 wherein the antimicrobial gas generating means is oriented so that the first direction is up and substantially vertical.

15 47. A method for testing sterilization processes that use a flowing antimicrobial gas comprising hydrogen peroxide vapor, or for testing materials for such processes, or for testing both such processes and such materials, the materials comprising one or more articles, the method comprising:

20 (a) flowing the antimicrobial gas to provide contact of any one or more articles with the antimicrobial gas when the articles are in the chamber of the apparatus of claim 30 or 38;

(b) flowing the antimicrobial gas in the chamber to contact any such one or more articles under substantially uniform conditions for the desired time, the flow of the antimicrobial gas in the chamber during the desired time being substantially continuous and the concentration of the hydrogen peroxide in the antimicrobial gas during the desired time being substantially
25 constant; and

(c) halting the flow of antimicrobial gas after the desired time has elapsed.